

SOP ON VICH PROCEDURE FOR THE WORKING GROUPS

INTRODUCTION

This document provides guidance to Working Group (WG) members on the operations of VICH. This document's objective is to explain the detailed rules and VICH procedures regarding the operations of the WGs. Another document "Guidance for Members of VICH Working Groups" (VICH/00/150) contains additional practical information regarding the functioning of the WGs.

A. THE VICH ORGANISATIONAL CHARTER

The VICH Organisational Charter (*ref: VICH/96/002*) is the basic document, i.e. the "constitution" of VICH. It lays down the objectives, the rules, the procedures of VICH as well as the status and the role of each participant in the VICH process.

The objectives of VICH are to:

- Provide a forum for a constructive dialogue between regulatory authorities and the veterinary medicinal products industry on the real and perceived differences in the technical requirements for product registration in the EU, Japan and the USA, with the expectation that such a process will lead to a wider international harmonisation.
- Identify areas where modifications in technical requirements or greater mutual acceptance of research and development procedures could lead to a more economical use of human, animal and material resources, without compromising safety.
- Make recommendations, in the form of guidelines, on practical ways to achieve harmonisation in technical requirements affecting registration of veterinary products and to implement these guidelines in the three regions. Once adopted the VICH guidelines should replace corresponding regional requirements. These guidelines should focus on the essential scientific requirements needed to address a topic and should eliminate unnecessary or redundant requirements.
- The VICH should be conducted in a transparent and cost-effective manner and should provide an opportunity for public comment on guidelines at the draft stage.

VICH achieves the technical development of guidelines through its WGs. The first WGs were set up in 1996. So far nine WGs have been set up of which two have already completed their tasks. In mid-2000, 24 VICH Guidelines or draft Guidelines have been issued by the WGs and a number of new draft documents are expected in the forthcoming months.

The VICH process is facilitated by the Office International des Epizooties (OIE), which as associate member of VICH is committed to communicating the activities and guidelines of VICH to its member countries.

WG members are encouraged to read the **Organisational Charter (VICH/96/002)** to fully understand VICH operations.

B. ROLES WITHIN VICH

1/ The Steering Committee (SC)

The SC drives the harmonisation process. The key tasks of the SC are to:

- Determine the operating rules and procedures for VICH
- Determine the priority items based on concept papers prepared by its members;
- Set up the appropriate WGs and appoint WG Topic Leaders and Chairpersons
- Approve the draft recommendations issued by WGs before release for world-wide consultation and subsequently for approval by the competent authorities of the EU, Japan and the USA

The SC meets twice a year on a rotational basis in the three regions who are members of VICH.

Full SC members: The Steering Committee is composed of two delegates each from the regulatory authorities and industry associations from the three regions i.e.:

- European Union
- Japanese government
- US government
- FEDESA
- JVPA/JAVB
- AHI

Observers: There are two observers to the SC

- Australia/New Zealand regulators represented by Australia National Registration Authority and New Zealand MAF Regulatory Authority - Agricultural Compounds Unit,
- the Industry of Australia/New Zealand represented by AVCARE/AGCARM

Associate member: There is one associate member to the SC: the OIE. The OIE has the opportunity to take part in the discussions of the SC, but it will not take part in any vote, nor will it sign-off on any VICH document.

Coordinators: Each SC member has appointed a coordinator to serve as the point of contact for their constituency and with the VICH secretariat. Coordinators ensure that VICH documents are distributed to the appropriate persons within the area of their responsibility and that the requested input is provided in a timely fashion. The Coordinators also liaise between working group experts, the Steering Committee and the VICH Secretariat

Secretariat: COMISA provides the secretariat for VICH activities. It also maintains the VICH web site.

2/ Working Groups (WG)

The WGs are task-oriented and their aim is to:

- Elaborate draft recommendations for the priority items determined by the SC;
- Submit these draft recommendations and the revised draft recommendations to the SC.

Membership of the Working Groups

The membership is decided by the SC.

- *Experts*

Each SC member and observer (hereafter called SC participant) have the right to appoint one expert. Each expert has the same status within the WG irrespective of whether they are appointed by a SC member or observer.

If necessary, and unless otherwise specified by the SC, each expert may be accompanied by one advisor. The chairperson, the topic leaders and the secretariat should be notified of this by the coordinator of the VICH member appointing the advisor.

The SC can appoint additional experts from other regions.

In order to respect the geographical balance, only one expert or advisor per SC member/observer should speak on a given topic.

Unless otherwise decided by the SC, no observers are allowed in the WG meeting.

- *Topic Leaders / Chairperson of WGs:*

A Topic Leader is appointed for each WG by the SC, on the basis of expertise and on geographical balance.

The Topic Leader is accountable to the SC with respect to the mandate and time frame given by the SC. He/She will also be responsible for preparing the appropriate discussion documents for the WG meetings.

A working group may be assigned several related topics. While each topic may be under the leadership and responsibility of a different Topic Leader, the Chairperson will be appointed by the SC and accountable to the SC with respect to the overall mandate and time frame of the WG activities. In this instance, each topic will still be under the leadership and responsibility of the Topic Leader.

The Topic Leader/Chairperson is responsible for making arrangements for a WG secretariat.

If the Topic Leader of a WG is an expert appointed by an industry SC participant, the role of topic leader must be passed to an expert appointed by a regulator and endorsed by the SC, once the draft guideline has proceeded to Step 5.

C. VICH PROCESSES FOR PRODUCING GUIDELINES

The 9 step procedure (VICH/00/008)

The development of VICH Guidelines follows a well-sequenced multi-step process:

- Step 1:** The Steering Committee defines a priority item from a concept paper prepared by a member and appoints a working group if needed. A topic leader is given a mandate to draft a recommendation.
- Step 2:** A recommendation is drafted and agreed by the working group.
- Step 3:** The draft is submitted to the VICH secretariat for SC approval.
- Step 4:** Following adoption by the SC, the draft guideline is circulated for consultation.
- Step 5:** The WG takes comments into consideration in preparing a revised draft. The Topic Leader must be a representative of a regulatory authority at this stage.
- Step 6:** The revised draft guideline is submitted to the VICH secretariat for SC approval.
- Step 7:** A final guideline and proposed implementation date are circulated to the relevant regulatory authorities.
- Step 8:** Steering Committee members report back on the implementation progress in their regions.
- Step 9:** Guidelines may be revised at the request of a member to take into account new scientific evidence.

D. PROCEDURE TO BE FOLLOWED BY THE SC AND WG TO GAIN AGREEMENT FOR THE FIRST WG MEETING

1

A VICH topic is selected by the SC from a concept paper.

A VICH Topic Concept paper should be based on the following format:

Purpose : To guide the SC in the selection of a topic

To be elaborated by : Any SC participant who wishes to propose a specific topic

Outline : Define the issue in detail, explaining where the differences in requirements are and what the impact these differences have for regulators and the industry

Specify the existing legislative requirements and/or relevant guidelines in the different regions

Proposal for an action plan. This should include the need for a new WG or proposal for coverage by an existing WG, the specific

expertise proposed, the number of meetings proposed, the various phases if appropriate, and the time frame

Suggested number of pages : 2 - 4

Suggested appendices : Tabulated comparison of specific requirements in the different regions

Existing legal requirements and/or relevant national guidelines

Relevant international guidelines (e.g. ICH, OECD, OIE, CODEX, JECFA)

WG members should obtain a copy of the concept paper for their particular topic from their coordinator. This paper (subject to any changes or decisions made by the SC) defines the scope of work of the WG.

2

A Topic Leader, or Chairperson and Topic Leaders, is appointed at a Steering Committee meeting.

3 2 months

Each SC member/observer can appoint one expert for the topic selected.

Name, affiliation, mailing address, telephone number, telefax number and e-mail address of the experts are to be provided to the VICH Secretariat by the coordinator of the SC member or the observer.

4 1 week

The VICH Secretariat sends out a list of members of the WG to the Chairperson (if appointed) or the Topic Leader, together with relevant documents:

- *Organisational charter of VICH (VICH/96/002)*
- *SOP on VICH procedures for the Working Groups (VICH/00/151)*
- *Guidance for members of VICH Working Groups (VICH/00/150)*
- *Notes on the format and style of VICH Guidelines (VICH/97/061)*

asking him/her to initiate action on the specific topic.

5 2 months

The Topic Leader will write a **discussion document** and establish the meeting schedule and action plan. The action plan must be presented and agreed to at the first WG meeting. Confirmation of the acceptance of the action plan should be sent to the VICH secretariat. The plan should be reviewed at each subsequent meeting and any proposed amendments submitted to the SC by the Topic Leader/ Chairperson through the Coordinator.

If a Chairperson is appointed, he/she will be responsible for establishing the meeting schedule and action plan and the Topic Leaders would prepare the discussion documents under the chairperson's direction.

In order to authorise the first meeting of the WG by the SC, the SC members need to receive from the Topic Leader a short discussion document in which the issues that are to be discussed, the meeting's schedule, and possibly first proposals should be outlined as follows

Purpose : Prepare thoroughly for the WG meeting

To be elaborated by : The Topic Leader (in consultation with the chairperson in the case of a WG with multiple topics)

Outline : Detailed description of all issues at stake on the topic concerned (i.e. differences in regulatory requirements and practices) using the concept paper prepared as a basis and taking into account the mandate outlined by the SC.

Proposal on ways to resolve issues, either as points for discussion, or even draft guidelines.

Proposed schedule and organisation, i.e. number, location and tentative schedule of meetings, and tentative target deadline for proposing guidelines text for submission to SC at step 3.

Suggested number of pages : 2 - 10

Suggested appendices : tabulated comparison of specific requirements in the different regions

existing legal requirements and/or relevant national guidelines

relevant international guidelines (e.g. ICH, OECD, OIE, CODEX, JECFA)

This document should be short but precise and sent to the VICH Secretariat.

6

In parallel with the elaboration of his/her document, the Topic Leader or Chairperson should, as soon as he/she is appointed, contact all the WGs experts and tentatively schedule the necessary meeting(s) so that they can take place as soon as possible after the SC authorisation.

7 1 week

The VICH secretariat sends the document received from the Topic Leader and Chairperson to the SC for authorisation of the meeting schedule and the action plan.

8 2 weeks

The SC authorises (or not) by written procedure the meeting schedule and the action plan as drafted by the Topic Leader and Chairperson.

9 1 week

The VICH secretariat notifies the Topic Leader and Chairperson of the authorisation given by the SC.

Note: These timelines are deadlines that should if possible not be exceeded. All involved should endeavour to reduce these timelines to the minimum feasible.

E. SEEKING PERMISSION FOR SUBSEQUENT MEETINGS AND LOCATION OF MEETINGS

Authorisation needs to be obtained from the SC for **each** WG meeting in order to consistently monitor the cost-efficiency of VICH. Authorisation is at SC meetings or by a written (sign-off) procedure.

The frequency of WG meetings is to be decided by the SC following a proposal of the Topic Leader/WG Chairperson.

All WG meetings are to be rotated among the three regions, starting in general with the region, which holds the chair of the WG.

F. CONSULTATION AT STEP 4

The procedures applied for consultation at step 4 are detailed in the document VICH/00/154.

G. CONDUCT OF MEETINGS

The working language is English. Any translation considered necessary by any expert or Topic Leader shall be provided by such experts and Topic Leaders at their own expense.

The Topic Leader/Chairperson of the WG ensures that at all times, all members of the WG are able to participate actively in the discussions and present their opinions and views to their colleagues. When necessary, adequate time should be allowed for simultaneous translation.

The Topic Leader/Chairperson of the WG will ensure that minutes of the meetings are produced in a timely fashion and sent immediately thereafter to the secretariat for circulation to the SC members.

H. ESTABLISHMENT OF A VICH TOPIC PROGRESS REPORT

Before each SC meeting, the SC members should receive a **progress report** on the progress and activities of each VICH topic.

Purpose : Report progress to SC

To be elaborated by : The Topic Leader. Alternatively, if several topics are grouped under one WG, this should be done by the Chairperson, with input from the topic leaders.

Outline : Describe the points agreed to by the WG members, thereby reflecting the degree of consensus

Provide a precise description of the points where there is no agreement with an indication of the different members positions

If needed, outline the areas where clarification or guidance from

the SC is being sought. The questions should be asked in a clear and unambiguous way

Proposal for the next steps with an estimate of the necessary time frame to complete the work

Suggested number : 2 – 4
of pages

I. PAYMENT OF EXPENSES

VICH does not provide any financial support for WG members. Each SC member/observer who appoints an expert/advisor is responsible for making his/her own arrangements for funding the travel and accommodation expenses of their appointee.

J. DISBANDING OF WORKING GROUP

(see document VICH/00/153)